

ANALYTICAL SERVICES

NCS Pharmaceuticals, LLC is a contract analytical testing laboratory, offering cGMP and GLP services to the pharmaceutical, medical device, food, dietary supplement, cosmetic, chemical, and allied industries. Our clients in the pharmaceutical industry range from suppliers of Bulk Drug Substances to manufacturers of brand name and/or generic Finished Drug Products. Our test procedures are based either on the FDA, ICH, ISO guidelines, USP/NF, BP, EP, JP monographs, or on the clients' SOPs. We specialize in the chemical analysis, dissolution testing, and stability testing of both non-controlled and controlled drug substances in schedules II thru V. Our testing capabilities include: HPLC, GC, Atomic Absorption Spectroscopy, and Mass spectrometry.

SERVICES OFFERED

- 1** Development of analytical methods (HPLC and GC) for the assay and purity of active/inactive pharmaceutical ingredients in drug products/drug substances.
- 2** Validation of HPLC and GC methods (assay and purity) for drug substances/drug products.
- 3** Transfer of validated analytical methods to different laboratories.
- 4** Stability studies on drug substances/drug products.
- 5** Identification of unknown impurities in drug substances/drug products by LC/MS and or GC/MS.
- 6** Characterization of peptides, proteins and industrial polymers using Matrix Assisted Laser Desorption Time Of Flight Instrument.
- 7** Elemental analysis using Atomic Absorption Spectroscopy.
- 8** Identification and Quantitation of both aqueous and volatile leacheable and extractable inorganic and organic chemical species from finished pharmaceuticals combination products such as drugs in disposable plastic syringes

STABILITY STUDIES CHECKLIST

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1. NCS Pharmaceuticals Project No.		
2. Project Title		
3. Client's Approved Protocol No.		
4. Project Contact(s)		
<p align="center">Technical Contact</p> Name: Title: Company Affiliation: Phone Number: Fax Number:		<p align="center">Business Contact</p> Name: Title: Company Affiliation: Phone Number: Fax Number:
5. Name of Drug Substance / Drug Product		
1) Packaging Configuration (check all applicable)		Parenteral Preparation: 1) Ampules, Size: _____ mL 2) Powder in a bottle, Size: _____ mL Tablet: 1) Blister packs, No. of Tablets _____ 2) Bottles, No. of Tablets _____ Suspension: 1) Bottles, Size: _____ mL Creams: 1) Tubes, Size: _____ gm. Liquids: 1) Bottles, Size: _____ mL
6. List the lot number for each Configuration		
7. Total quantity of samples needed for Stability put-up		

STABILITY STUDIES CHECKLIST

<p>8. Environmental conditions: (check all the necessary conditions and mention duration of each study)</p>	<ul style="list-style-type: none"> • 5°C / amb. RH, ____ months • 25°C / 60% RH, ____ months • 30°C / 60% RH, ____ months • 40°C / 75% RH, ____ months • Other: _____, ____ months • Cycling: _____, ____ weeks • Photostability –ICH Option 1-XENON TEST CHAMBER • Photostability: ____ FC/Lux, ____ days (ICH-Option 2)
<p>9. Pull schedules</p>	<ol style="list-style-type: none"> 1. 0 month 2. 1 month 3. 3 months 4. 6 months 5. 9 months 6. 12 months 7. 18 months 8. 24 months 9. 36 months
<p>10. Tests to be performed (check all applicable and list methods)</p>	<ul style="list-style-type: none"> ➤ Appearance, STM _____ ➤ Assay, STM _____ ➤ Purity, STM _____ ➤ pH, STM _____ ➤ Dissolution, STM _____ ➤ Particulate matter, STM _____ ➤ Volume in container, STM _____ ➤ Weight loss, STM _____ ➤ Viscosity, STM _____ ➤ Disintegration time, STM _____ ➤ Hardness, STM _____ ➤ Friability, STM _____ ➤ Sterility, STM _____ ➤ Endotoxins, STM _____
<p>11. Stability reporting format (to be given by client)</p>	
<p>12. Study start date</p>	
<p>13. Study completion date</p>	
<p>14. Mode of sample disposal (if controlled substance)</p>	

DEVELOPMENT, VALIDATION & TRANSFER OF ANALYTICAL METHODS CHECKLIST

1. NCS Pharmaceuticals Project No.		
2. Project Title:		
3. Name of Drug Substance/Drug Product		
4. Project Contact(s)		
<p align="center">Technical Contact</p> Name: Title: Company Affiliation: Phone Number: Fax Number:		<p align="center">Business Contact</p> Name: Title: Company Affiliation: Phone Number: Fax Number:
5. Analyte for which method is to be developed (list the strength in case of drug product, mg/mL or mg/tablet)		
6. Packaging Configuration (check all Applicable)		Parenteral Preparation: 1 Ampules, Size: _____ mL 2 Vials, Size: _____ mL 3 Powder in a bottle, Size: _____ mL Tablet: 4 Blister packs, No. of Tablets _____ 5 Bottles, No. of Tablets _____ Suspension: 6 Bottles, Size: _____ mL Creams: 7 Tubes, Size: _____ gm. Liquids: 8 Bottles, Size: _____ mL

DEVELOPMENT, VALIDATION & TRANSFER OF ANALYTICAL METHODS CHECKLIST

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7. Select method(s) to be developed	1 Assay: a) HPLC b) GC 2 Purity: a) HPLC b) GC 3 Dissolution
8. Placebo available	1 Yes 2 No
9. List the identity of degradants (R compounds)	
10. Method Development start date	
11. Anticipated completion date	
12. Validation protocol assembled by	1 NCS Pharmaceuticals 2 Client
13. Drug product lot numbers used for Validation	
14. Anticipated validation start date	
15. Anticipated completion date	
16. Method transfer protocol assembled by	1 NCS Pharmaceuticals 2 Client
17. Method receiving laboratory	
18. Drug product lot numbers used for Validation	
19. Anticipated validation start date	
20. Anticipated completion date	

IDENTIFICATION OF UNKNOWN IMPURITIES BY LC/MS and or GC/MS CHECKLIST

1. NCS Pharmaceuticals Project No.		
2. Project Title		
3. Name of Drug Substance/Drug Product		
4. Project Contact(s)		
<p align="center">Technical Contact</p> Name: Title: Company Affiliation: Phone Number: Fax Number:		<p align="center">Business Contact</p> Name: Title: Company Affiliation: Phone Number: Fax Number:
5. Strength of drug product	_____ mg/mL _____ mg/ tablet _____ mg/gm	
6. Packaging configuration (check all applicable)	Parenteral Preparation: 1 Ampules, Size: _____ mL 2 Vials, Size: _____ mL 3 Powder in a bottle, Size: _____ mL Tablet: 1 Blister packs, No. of Tablets _____ 2 Bottles, No. of Tablets _____ Suspension: 1 Bottles, Size: _____ mL Creams: 1 Tubes, Size: _____ gm. Liquids: 2 Bottles, Size: _____ mL	
7. Lot number(s) of drug product/drug substance under investigation		
8. List method(s) used	1) Assay: HPLC GC 2) Purity: HPLC GC	

IDENTIFICATION OF UNKNOWN IMPURITIES BY LC/MS and or GC/MS CHECKLIST

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9. Placebo available	<ul style="list-style-type: none"> ➤ Yes ➤ No
10. List the identity of degradants (R compounds)	Available: Yes or No
11. Select services needed	<ul style="list-style-type: none"> ➤ Molecular weight by MALDI-TOF ➤ Molecular weight by LC-ESI/APCI/MS ➤ Structural details by LC-ESI/APC/MS-MS ➤ GC/MS –EI/CI for volatiles components and also for Non-polar and polar compounds ➤ UV spectra by PDA ➤ Co-injection with known R compound ➤ Leacheable and extractable chemical species ➤ Impurity investigation in a finished product. ➤ Characterization of Industrial Polymers
12. Study start date	
13. Anticipated completion date	