

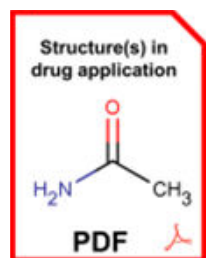
NEW US FDA Structure-Data File Format (SD)

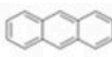
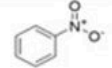
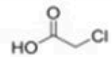
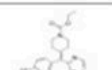
Are you planning
to submit a DMF to FDA?
Are you holding a
DMF Type II?

If the answer is YES,
this brochure may be
of your interest!

Since October 1st, 2022, the SD File needs
to be included in US FDA DMF Type II submissions

DMF holders may now provide SD Files (.sdf) through eCTD
New Method of Processing and Registering Chemicals



Sample SD File						
Structure	ID	NAME	UNII	CAS	ROLE	APPLICATION _NUMBER
	Structure 1	anthracene	EH46A1TLD7	120-12-7	process impurity	MF-012345
	Structure 2	nitrobenzene	E57JCN6SSY	98-95-3	starting material	MF-012345
	Structure 3	2- chloroacetic acid	5GD84Y125G	79-11-8	starting material	MF-012345
	Structure 4	loratadine	7AJ03BO7QN	79794-75-5	active ingredient	MF-012345

The **SD** (Structure-Data) file is an extensible, portable text file encoding computer- readable chemical structures linked to associated data fields.

Asphalion can support your company creating the SD File using chemical software and publishing it in eCTD format within your DMF (Drug Master File) dossier lifecycle.